European Food Safety Authority

GMO Unit

Opinion of the European Food Safety Authority in accordance with Articles 6 and 18 of Regulation (EC) No. 1829/2003 on application EFSA-GMO-NL-2007-37

Application for the placing on the market of insect resistant genetically modified maize MON89034 for food and feed uses from Monsanto.

(Question No. EFSA-Q-2007-042)

18 December 2008

Summary

This document provides an overall opinion of the European Food Safety Authority on genetically modified maize MON89034 in accordance with the requirements of Articles 6 and 18 of Regulation (EC) No 1829/2003.

The scope of this application is genetically modified maize MON89034 for food and feed uses[1], food and feed containing, consisting of or produced from maize MON89034. The scope does not include cultivation.

The Scientific Panel on Genetically Modified Organisms has carried out the scientific assessment of genetically modified maize MON89034 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and considers that the genetically modified maize MON89034 is unlikely to have any adverse effect on human and animal health or on the environment in the context of its intended uses.

The Community Reference Laboratory considers the method validated as fit for the purpose of regulatory compliance. The certified reference materials of maize MON89034 can be accessed at the American Oil Chemists' Society (AOCS– USA).

The information presented for the Cartagena Protocol, the labelling proposal and the monitoring plan are in line with Regulation (EC) No 1829/2003.

Under the terms of the Regulation (EC) No 1829/2003, the overall opinion fulfils the requirements of Articles 6 and 18 for the placing on the market of genetically modified maize MON89034.

[1] This does include GM maize MON89034 for import and processing as designated under part C of Directive 2001/18/EC

Address for correspondence:
European Food Safety Authority (EFSA)
Largo N. Palli 5/A, 43100 Parma - Italy
Telephone: +39 0521 036 111 - Fax: +39 0521 036 110 – www.efsa.europa.eu

Background

On 31 January 2007, the European Food Safety Authority (EFSA) received from the Competent Authority of the Netherlands an application for authorisation of GM maize MON89034 (MON-89Ø34-3) submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on genetically modified food and feed (reference EFSA-GMO-NL-2007-37).

The scope of this application is genetically modified maize MON89034 for food and feed uses[2], food and feed containing, consisting of or produced from maize MON89034. The scope does not include cultivation.

In accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, EFSA informed the Member States and the European Commission and made the summary of the application publicly available on the EFSA website[3] on 27 August 2007. EFSA initiated a completeness check of the application to check compliance with the requirements laid down in Articles 5 and 17 of Regulation (EC) No 1829/2003. On 21 December 2006, 25 March 2007 and 30 May 2007, the Community Reference Laboratory (CRL) confirmed receipt of the detection method, samples and control samples in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. EFSA declared the application valid on 24 August 2007 and started the clock in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003.

From that date, EFSA has endeavoured to respect a time limit of 6 months in giving its overall opinion (Articles 6(1) and 18(1)). EFSA made the valid application available to Member States and the European Commission. Following the procedure laid down in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, EFSA consulted the Member States. In this context, the Member States risk assessment bodies, as well as the national competent authorities under Directive 2001/18/EC, were given three months after the date of receipt of the valid application (*i.e.* until 24 November 2007) within which to make their opinion known.

Making use of the provisions under Articles 6(2) and 18(2), EFSA requested additional information from the applicant and the clock was stopped from 29 August 2007 to 25 November 2008 [4].

The overall opinion on application EFSA-GMO-NL-2007-37 includes the scientific opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) together with the particulars required under Articles 6(5)(a-g) and 18(5)(a-g) of Regulation (EC) No 1829/2003: i) the name and address of the applicant, ii) the designation of the food and its specification, iii) the information required under Annex II to the Cartagena Protocol, iv) the labelling proposal, v) the

[2] This does include GM maize MON89034 for import and processing as designated under part C of Directive 2001/18/EC

[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-042

[4] Request for additional information from EFSA-GMO Panel: requested (1) on 27/11/2007 - received on 10/12/2007, requested (2) on 21/01/2008 - received on 14/02/2008 and 18/02/2008, requested (3) on 27/02/2008 - received on 08/05/2008, requested (4) on 02/07/2008 - received on 04/08/2008, requested (5) on 20/10/2008 - received on 30/10/2008, and clock restarted on 25 November 2008.
Request for additional information from EFSA-JRC: requested on 29/08/2007, accepted on 18/10/2007.

method for detection, validated by the Community Reference Laboratory, including sampling, identification of the transformation event in the food-feed and/or foods-feeds produced from it, vi) an indication of where appropriate reference materials can be accessed, vii) the monitoring plan and viii) Member States' comments submitted during the three-month consultation period.

Applicant

The application was submitted by

Monsanto Europe S.A.
Avenue de Tervuren 270-272
B-1150 Brussels
Belgium

Monsanto Company
800 N. Lindbergh Boulevard
St Louis, Missouri 63167
U.S.A.

Designation and specification of the product

The scope of this application is genetically modified maize MON89034 for food and feed uses[5], food and feed containing, consisting of or produced from GM maize MON89034. The scope does not include cultivation.

Genetically modified maize MON89034 expresses the Cry1A.105 and Cry2Ab2 proteins to confer tolerance to certain insect pests

Scientific opinion of the GMO Panel

The GMO Panel has carried out the scientific assessment of the genetically modified maize MON89034 in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003 and adopted its scientific opinion on 3 December 2008. The GMO Panel considered all comments submitted by Member State bodies and where deemed necessary, requested additional information from the applicant before finalising its scientific assessment. The GMO Panel concludes that the information available for GM maize MON89034 addresses the scientific comments raised by the Member States and considers that GM maize MON89034 is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses (Annex A).

Cartagena Protocol

The information presented in the application and as required under Annex II of the Cartagena Protocol on Biosafety is in line with the scientific opinion of the GMO Panel (Annex B).

Labelling

The labelling proposal provided in the application is in line with the requirements in Regulation (EC) No 1829/2003. On the basis of the scientific opinion of the GMO Panel that GM maize

[5] This does include GM maize MON89034 for import and processing as designated under part C of Directive 2001/18/EC

MON89034 is compositionally and phenotypically equivalent to its non-genetically modified maize MON89034 except for the introduced traits, EFSA is of the opinion that there is no need for a specific labelling in accordance with Articles 13(2)(a) and 25(2)(c) (Annex C).

Method for detection

The Joint Research Centre (JRC) as Community Reference Laboratory for the GM Food and Feed has carried out a collaborative study to assess the performance of a quantitative event-specific method to detect and quantify the MON89034 transformation event in maize DNA. The reports were published on 13 and 21 October 2008. The Community Reference Laboratory considers that the method is applicable to the control samples provided, in accordance with the requirements of Annex I-2.C.2. to Commission Regulation (EC) No 641/2004 (Annexes D1, D2, D3).

Certified reference materials

The certified reference materials of genetically modified maize MON89034 can be accessed at the American Oil Chemists' Society AOCS (Annex E).

Post market environmental monitoring

The GMO Panel evaluated the environmental monitoring plan proposed by the applicant. The GMO Panel considered that the monitoring plan provided by the applicant is in line with the intended uses for the GMO (Annex F).

Member States' Comments

The GMO Panel has addressed the comments submitted by the Member States during the three months consultation period (Annex G).

List of annexes:

Annex A:	Scientific opinion of the GMO Panel (maize MON89034)
Annex B:	Cartagena Protocol (maize MON89034)
Annex C:	Labelling (maize MON89034)
Annex D1:	Validation report (maize MON89034)
Annex D2:	Validated method (maize MON89034)
Annex D3:	Sampling and extraction (maize MON89034)
Annex E:	Certified reference materials report (maize MON89034)
Annex F:	Post market monitoring plan (maize MON89034)
Annex G:	Member States' comments (maize MON89034)